

January 24, 1994

TO: NOSB Members

FOR: Discussion at January Board Meeting

FROM: NOSB Executive Committee Biotech Task Force:
Margaret Clark and Richard Theuer

SUBJECT: Proposed Position on Organisms created by Recombinant DNA and their Products in Organic Food Production and Handling Systems.

Attached is a one page document which represents months of collaboration and discussion between ourselves and many others, towards finding a basic understanding of "bioengineering" as it relates to organic agriculture. This document is not exhaustive nor comprehensive of all input received by the NOSB on this subject. We have looked at other bioengineering technologies besides r-DNA, and feel we are close to agreement on the suitability of most of them for organic agriculture; we feel, however, that as r-DNA is the clear focus of most public concern, it is the first and most important class of bioengineering processes for the Board to consider.

As you look at the attached document, consider our conclusions (1) thru (5) as a "step-by-step" map for discussion purposes at our meeting in Alexandria. We believe it reflects the logic necessary to consider this subject within the parameters of the OFPA.

A longer discussion piece with more background, definitions, and legal analysis and a position paper are being prepared by an OFPANA task force, and will be sent to you by them soon. A listing of letters sent to us on the subject has been prepared by NOP staff and will also be sent to you, with copies of these letters. We, Rich and Margaret, will be happy to discuss this with you further, and to share references we have used. Thank you for giving this your consideration; looking forward to good discussion.

Proposed Position Paper on Organisms Created by Recombinant DNA Technology and the Products of these Organisms. 1/2/94

"Biotechnology" and "Bioengineering" are terms used to cover processes as disparate as fermentation of beer and use of recombinant DNA (r-DNA) technology. They are thus too broad to be useful for our discussion. The issue here is recombinant DNA.

Recombinant DNA technology is the synthetic process for creating a transgenic organism, in which the genetic material from one species is inserted into the genetic material of another species. According to the OFPA, a substance is synthetic if it is produced other than by naturally occurring biological processes. R-DNA technology is clearly an "other than naturally occurring biological process." Therefore, any substance resulting therefrom is a synthetic substance. The use of synthetic substances in the production or handling of organic agricultural products is categorically prohibited by the OFPA.

The prohibition against synthetics is not absolute. Synthetic substances can be allowed under specific exemption if they can be shown to meet certain strict statutory criteria [OFPA § 6517 (c) (1) (A) and (B)]. In such cases, synthetic substances can be permitted as "allowed synthetics" on the National List.

We conclude the following:

- (1) Transgenic organisms and their products constitute a class of synthetic substances;
- (2) The use of transgenic organisms and their products in the production and handling of organic agricultural products is thus generally prohibited.
- (3) To be exempt for use in the production and handling of organic agricultural products, individual substances must be proven to satisfy all criteria for listed in [OFPA op cit];
- (4) Satisfying the requirement "that the use of such substances would not be harmful to human health or the environment" will be difficult, intentionally so. (NOTE 1.)
- (5) Proving that using such substance is "necessary...because of the unavailability of a wholly natural substitute," and that its use "is consistent with organic farming and handling" will be difficult as well. [OFPA op cit]

NOTE 1: Based on historical examples of delayed appearance of adverse health effects or environmental degradation after the introduction of exotic species and new synthetic substances (e.g., fluorinated hydrocarbon refrigerants and ozone depletion; diethylstilbestrol and breast cancer in daughters of DES-treated women; dioxins and endometriosis; rabbits in Australia; French snails and salad dandelions or African bees in the Western Hemisphere; etc.) the burden of proof of lack of adverse environmental or human health impact falls on the agent who wishes to introduce a synthetic into organic agriculture. The time period required for confirming the lack of adverse effects of xenobiotic species or substances could be 20 to 30 years, or more.

Rich Theuer and Margaret Clark 1/2/94